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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,732	01/15/2004	Oren A. Mosher		6876

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EXAMINER	
GIBSON, ROY DEAN	
ART UNIT	PAPER NUMBER
3739	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,732	MOSHER ET AL.	
	Examiner	Art Unit	
	Roy D. Gibson	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-21,23-28 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-21,23-28 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Entry of Amendment

Applicant's amendment filed on Sep. 29, 2006, acknowledged. Claim 22 has been claims 1-17,19-21, 23-28 and 36-44 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action, mailed on June 29, 2006. Rejections under 35 U.S.C. 102, as corrected, and 103 are repeated as presented below with comment. These corrections result in this Office action being non-final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-28 and 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ingle et al. (U.S. Patent No. 6,091,995 or 6,216,704).

In regards to Claim 23, Ingle et al. discloses a system for treating incontinence comprising "a probe body" (See Figure 1 , element 10) and that "at least one energy delivery element" (See Figure 1, elements 18 and 20).

The examiner agrees with the volume calculation presented on page 3 of the Remarks filed 9/29/2006, that the treatment volume treated would be about 268 cu. mm.

Note: Another similar patent by Ingle et al. e.g., P/N 6,216,704 disclose various embodiments that have treatment volumes greater than 300 cu. mm (see Figure 5, where the tip diameter can be 4 cm, providing an electrode width of about 20-30 mm and the electrode length is estimated as 10 mm resulting in a treatment volume of about 540 –800 cu. mm if the treatment depth is about 2.8 mm). However, see the new 103 rejection of claim 23 below.

In regards to Claim 24, Ingle et al. ('995) discloses a system for treating incontinence (See Claim 23 Rejection). Ingle et al. further discloses, "at least one cooling element supported by the probe body" (See column 13, lines 57-59).

In regards to Claim 25, Ingle et al. discloses a system for treating incontinence (See Claim 24 Rejection). Ingle et al. further discloses, "at least one energy delivery element comprises a plurality of electrodes" (See column 22, line 63 - column 23, line 4).

In regards to Claim 26, Ingle et al. discloses a system for treating incontinence (See Claim 25 Rejection). Ingle et al. further discloses, "the electrodes have a width of at least 20 mm and a length of less than 8 mm" (See column 4, lines 39-47', see also column 7, lines 30-32). Note that a max. electrode diameter of 4 mm each and a separation of 12 mm provides a width of 20 mm and a length of less than 8 mm.

In regards to Claim 27, Ingle et al. discloses a system for treating incontinence (See Claim 25 Rejection). Ingle et al. further discloses, "at least one energy delivery element comprises a distal or proximal pair of electrodes on the probe body" (See Figure 1 , elements 18 and 20).

In regards to Claim 28, Ingle et al. discloses a system for treating incontinence (See Claim 24 Rejection). Ingle et al. further discloses, "at least one energy delivery element comprises a pair of elongated electrodes" (See Figure 12A, elements 56 and 58).

In regards to Claims 38, 39, 40 and 43, Ingle et al. discloses a system for treating incontinence (See Claim 23 Rejection). Ingle et al. further discloses, "the treatment volume comprises tissue separated from the aligned probe body by a distance within a range of about 2 to 8 mm" and "the treatment volume is separated from a urethra by at least about 1 cm" (See column 6, lines 22-35), "the treatment volume is offset laterally from the urethra to a right side or left side" (See Figure 4 and column 12, lines 3-12) and "the treatment volume comprises between about 300 cubic millimeters and about 800 cubic millimeters of collagenous tissue" (See column 4, lines 29-33). It is the Examiner's position that Ingle et al. is inherently capable of meeting these functional limitations.

In regards to Claims 41 and 42, Ingle et al. discloses a system for treating

incontinence (See Claim 23 Rejection). Ingle et al. further discloses "the treatment volume has a length orientation extending along the urethra, a depth orientation extending between collagenous tissue and the probe body, and a width that is greater than the length of the treatment volume" or "the treatment volume has a length orientation extending along the urethra, a depth orientation extending between collagenous tissue and the probe body, and a width that is less than the length of the treatment volume" (See column 6, lines 22-35). It is the Examiner's position that Ingle et al. is inherently capable of meeting these functional limitations.

In regards to Claim 44, Ingle et al. discloses a system for treating incontinence (See Claim 23 Rejection). Ingle et al. further discloses "at least one energy delivery element heats the treatment volume of tissue by the application of bipolar radio frequency energy" (See column 10, lines 21-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al. (U.S. Patent No. 6,091,995).

In regards to Claim 1, Ingle et al. discloses a method for treating

incontinence comprising, "aligning a probe body" (See column 4, lines 23-26). and heating a treatment volume of approximately 100 or 300 cubic millimeters and greater of the collagenous tissue". The examiner maintains that 268 cu. mm calculated by the applicant is "about 300 cu. mm") or that P/N 6,216,704 could also be used to reject the claim as presented above regarding claim 23.

In regards to Claim 2, Ingle et al. discloses a method for treating incontinence (See Claim 1 Rejection). Ingle et al. does not discloses "the treatment volume is separated from a urethra by at least about 1 cm". It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teaching of the Ingle et al. reference to treat a volume at least 1 cm apart from the urethra because one of ordinary skill in the art would be able to direct treatment to the optimum tissue location (See column 6, lines 22-35).

In regards to Claim 3, Ingle et al. discloses a method for treating incontinence (See Claim 2 Rejection). Ingle et al. does not discloses "the treatment volume is offset laterally from the urethra to a right side or left side. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teaching of the Ingle et al. reference to position the treatment probe in the optimum tissue location to relieve patient discomfort (See Figure 4., see also column 12, lines 3-12).

In regards to Claim 4, Ingle et al. discloses a method for treating

incontinence (See Claim 2 Rejection). Ingle et al. further discloses, "the treatment volume is heated to a temperature of at least 70 deg.C for a time of at least 30 seconds" (See column 21, lines 18-24). Ingle et al. does not disclose "the treatment volume comprises at least 300 cubic millimeters of collagenous tissue" and "the treatment volume is offset laterally from the urethra to a right side of a patient" or "the treatment volume is offset laterally from the urethra to a left side of a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teaching of Ingle et al. to heat a treatment volume of at least 300 cubic millimeters and the treatment volume is offset laterally from the urethra to a right side or left side of the patient because one of ordinary skill in the art would be able to determine the optimum area to treat to relieve patient discomfort (See column 4, lines 29-33 and See Figure 4,. see also column 12, lines 3-12).

In regards to Claim 5, Ingle et al. discloses a method for treating incontinence (See Claim 1 Rejection). Ingle et al. fudher discloses "the treatment volume is heated to at least about 65 deg. C for at least about 100 seconds" (See column 4, lines 30-34 and See column 21 , lines 18-24).

In regards to Claim 6, Ingle et al. discloses a method for treating incontinence (See Claim 1 Rejection). Ingle et al. further discloses "the treatment volume is heated to at least about 75 deg. C for at least about 10 seconds" (See column 21, lines 18-24).

In regards to Claim 7, Ingle et al. discloses a method for treating incontinence (See Claim 1 Rejection). Ingle et al. further discloses, "applying a dwell time after a desired heating temperature is achieved so as to increase treatment tissue volume" (See column 21, lines 18-24 and See column 22, lines 51 -52).

In regards to Claims 8 and 9, Ingle et al. discloses a method of treating incontinence (See Claim 1 Rejection). Ingle et al. does not disclose "the treatment volume has a length orientation extending along the urethra, a depth orientation extending between collagenous tissue and the probe body, and a width that is greater than the length of the treatment volume" or "the treatment volume has a length orientation extending along the urethra, a depth orientation extending between collagenous tissue and the probe body, and a width that is less than the length of the treatment volume". It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Ingle et al. reference because one of ordinary skill in the ad would be able to determine the optimum volume necessary to treat to relieve patient discomfort (See column 23, lines 31-50).

In regards to Claims 10 and 11, Ingle et al. discloses a method of treating incontinence (See Claim 1 Rejection). Ingle et al. further discloses, "registering a

position of the treatment volume along an axis of the urethra with reference to a guide body disposed within the urethra" and "registering a position of the treatment volume with reference to bone" (See column 6, lines 6-21).
In regards to Claim 12, Ingle et al. discloses a method of treating incontinence (See Claim 1 Rejection). Ingle et al. further discloses, "the probe is aligned so that an intermediate tissue is disposed between the probe body and the treatment volume" (See column 23, lines 31-50).

In regards to Claims 13 and 14, Ingle et al. discloses a method of treating incontinence (See Claim 12 Rejection). Ingle et al. does not disclose, "the treatment volume comprises tissue separated from the aligned probe body by a distance within a range of about 2 to 8 mm" or "the treatment volume comprises tissue separated from the aligned probe body by a distance within a range of about 2 to 4 mm". It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Ingle et al. reference because one of ordinary skill in the ad would be able to determine the optimum distance to locate the treatment volume to relieve patient discomfort (See column 6, lines 22-35).

In regards to Claim 15, Ingle et al. discloses a method of treating incontinence (See Claim 12 Rejection). Ingle et al. further discloses, "heating is performed so as to inhibit necrosis of the intermediate tissue" (See column 13, lines 44-54).

In regards to Claim 16, Ingle et In al. discloses a method of treating incontinence (See Claim 15 Rejection). Ingle et al. further discloses, "heating is performed while cooling of the intermediate tissue" (See column 13, lines 49-59).

In regards to Claim 17, Ingle et al. discloses a method of treating incontinence (See Claim 15 Rejection). Ingle et al. further discloses, "heating is performed without cooling of the intermediate tissue" (See column 21, lines 4-11).

In regards to Claim 19, Ingle et al. discloses a method of treating incontinence (See Claim 1 Rejection). Ingle et al. further discloses, "heating is performed by tip movement of at least a pair of electrodes supported by the probe body" (See column 12, lines 3-23).

In regards to Claim 20, Ingle et al. discloses a method of treating incontinence (See Claim 19 Rejection). Ingle et al. does not disclose, "the treatment volume increases as the tip movement speed decreases". It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Ingle et al. reference because one of ordinary skill in the art would be able to determine the tip movement speed necessary to treat the optimum treatment volume (See column 21, lines 18-28).

In regards to Claims 21 and 22, Ingle et al. discloses a method of treating incontinence (See Claim 1 Rejection). Ingle et al. does not disclose, "the treatment volume comprises at least 300 cubic millimeters of collagenous tissue" and "the treatment volume comprises between about 100 cubic millimeters and about 800 cubic millimeters of collagenous tissue". It would obvious to one of ordinary skill in the art at the time of the invention to use the Ingle et al. reference to heat a treatment volume of at least 300 cubic millimeters or between 100 and 800 cubic millimeters because one of ordinary skill in the art would be able to determine the optimum area to treat to relieve patient discomfort (See column 4, lines 29-33).

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al. (U.S. Patent No. 6,091,995) in view of Presthus et al. (U.S. Patent No. 6,685,623).

In regards to Claim 36, Ingle et al. discloses a system for treating incontinence (See Claim 23 Rejection). Ingle et al. does not disclose "a guide body disposable within a urethra". Attention is directed to the Presthus et al. reference, which in an analogous field of endeavor discloses a guide body or shaft used to assist in the proper positioning of the probe body and treatment surface with the target tissue (See Presthus et al. column 4, lines 36-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ingle et al. with the device of Presthus et al. to accurately position a treatment surface adjacent a target tissue.

In regards to Claim 37, Ingle et al. discloses a system for treating incontinence (See Claim 36 Rejection). Ingle et al. does not disclose "the guide body further comprises axial position indicators or electromagnetic transmitters". Attention is directed to the Presthus et al. reference, which in an analogous field of endeavor discloses a guide body with serrations that allow for incremental axial positioning (See Presthus et al. column 6, lines 51-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ingle et al. with the device of Presthus et al. to accurately position a treatment surface adjacent a target tissue.

Claims 1 and 23 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al. (6,091,995 or 6,216,704). The examiner maintains that at the time of the invention it would have been obvious to one of ordinary skill in the art to select the electrode size as required to treat the appropriate area/volume based upon the size of the patient (child or adult) and that this would typically be within the broad range claimed (300-800 cu. mm).

Further regarding claim 23, the examiner maintains that the device of Ingle et al. is fully capable of heating at least 300 cu. mm of tissue to at least 70 deg. C for at least 30 seconds (intended use in a device claim).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy D. Gibson
Primary Examiner
Art Unit 3739

December 11, 2006